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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,080	03/31/2004	Wallace Lynn Smith	MacBride86067-001	5650
7590 08/18/2005			EXAMINER	
William L. MacBride, Jr. 33 South Last Chance Gulch Helena, MT 59601			ASTORINO, MICHAEL C	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 08/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/813,080

Applicant(s)

SMITH, WALLACE LYNN

Examiner

Michael C. Astorino

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/3/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/3/2004</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter since the claimed invention fails to produce a useful, tangible, and concrete result.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter that fails to produce a useful, tangible, and concrete result. The claimed invention does not produce a “tangible” result in the sense that it merely manipulates abstract ideas without producing a physical transformation or conversion of the subject matter expressed in the claim to produce a change of character or condition in some physical object. See In re Warmerdam, 31 USPQ2d 1754 (Fed. Cir. 1994); In re Schrader, 30 USPQ2d 1445 (Fed. Cir. 1994). A method of diagnosing a probability of pain relief through medical treatment in a patient and the steps claimed is no more than a manipulation of an abstract idea.

In this case, the method comprises, according to claim 1, steps 1(a)-(q). The steps include administering a perceptual test, receiving responses, providing and applying scoring templates, etcetera, until values are summed to produce a pain index score. These steps are not a tangible entities having substance. As such, claim 1 recites the manipulation of abstract ideas, lacks practical utility, and fails to achieve a useful, concrete, and tangible result.

Secondly, the method of diagnosing a probability of pain relief through medical treatment in a patient does not produce concrete, substantially repeatable results. Otherwise stated, it is extremely unlikely that two separate people with the same actual probability of pain relief through medical treatment will answer the same questions the same way to produce the same outcome. Or, the same patient will respond to the same questions with the same answers to produce the same results. In either case, the method is not substantially repeatable.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The lacking specific and substantial asserted utility is directed to the lack of substantially repeatability.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner if the applicant is claiming alternative limitations.

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Specifically as to claim limitations 1(c), 1(d), they fail to provide for alternative limitations.

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. In this case the applicant appears to be claiming an alternative expression, yet logically no alternative can be completed. Otherwise stated, in claim 1(c) the applicant claims "providing at least three scoring templates...selected from the group of validity factors...defensiveness, predictiveness, and carelessness." The limitation drafted in this manner creates only one possibility exists-no alternatives exist. The one possibility is defensiveness, predictiveness, and carelessness being the three scoring templates. In regards to the claim limitation 1(d), the same error exists, only with six instead of three factors.

Additionally, the applicant should review claim limitations 1(g), 1(i), and 1(k) to be certain the applicant's intentions are accurately represented. See MPEP 2173.05(h)

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin et al.

"Predicting Surgical Outcome for Pain Relief and Return to Work." (cited by applicant).

In regards to claims 1-2, Hamlin et al. teaches the use of the Painindex analysis yielding a Pain Index Score and a Probability Equation score. The Painindex test is taught as having three validity scales and ten clinical scales. Additionally, the Pain Index score is calculated using the

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10 scales of the MMPI clinical profiles. (See entire document, particularly the subheading Patients and Methods.)

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael C Astorino** whose telephone number is **571-272-4723**. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in dark ink, appearing to read 'Michael Astorino', with a long horizontal stroke extending to the right.

Michael Astorino  
August 12, 2005